DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#22

Food and Drug Administration
Rockville MD 20857

APR - 8 1994

Re: Mycobutin™
Docket No. 93E-0089

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,219,478, filed by Adria Laboratories under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Mycobutin™, the human drug product claimed by the patent.

The total length of the review period for Mycobutin™ is 2831 days. Of this time, 2124 days occurred during the testing phase and 707 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 23, 1986.

   The applicant claims April 18, 1986, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 23, 1986, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 507 of the Federal Food, Drug, and Cosmetic Act: January 17, 1992.

   The applicant claims January 16, 1992, as the date the new drug application (NDA) for Mycobutin™ was initially submitted. However, FDA records indicate that the new drug application (NDA 50-689) was initially submitted on January 17, 1992.

3. The date the application was approved: December 23, 1992.

   FDA has verified the applicant's claim that NDA 50-689 was approved on December 23, 1992.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Mark P. Levy, Esq.
Thompson, Hine & Flory
P.O. Box 8801
2000 Courthouse Plaza, N.E.
Dayton, Ohio 45401-8801

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR -8 1994

Re: Mycobutin™
Docket No. 93E-0099

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

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